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CytoDyn Announces First Patient Dosed in Expanded Access Program for Leronlimab in Triple-Negative Breast Cancer

Program provides access to leronlimab for patients with limited treatment options while supporting ongoing clinical development

VANCOUVER, Washington, April 27, 2026 (GLOBE NEWSWIRE) -- **CytoDyn Inc. (OTCQB: CYDY)** ("CytoDyn" or the "Company"), a clinical-stage oncology company advancing leronlimab, a first-in-class humanized monoclonal antibody targeting the CCR5 receptor with therapeutic potential across multiple indications, including metastatic triple-negative breast cancer (“mTNBC”) and colorectal cancer (“mCRC”), today announced the successful enrollment and initial dosing of the first participant in its Expanded Access Program (EAP) for patients with triple-negative breast cancer (TNBC).

The EAP is designed to provide eligible patients access to leronlimab outside of a clinical study setting. The program is intended for patients who have exhausted available treatment options and are not eligible for ongoing or planned clinical studies, in accordance with U.S. Food and Drug Administration (FDA) guidelines.

“Dosing the first patient in our EAP marks an important step in making leronlimab available to individuals with urgent unmet medical needs, while also advancing our understanding of CCR5 biology in the treatment of aggressive cancers,” said Jacob Lalezari, M.D., CEO of CytoDyn. “Data generated through this program may further inform how CCR5 inhibition influences the tumor microenvironment, including its potential role in modulating PD-L1 expression and supporting combination approaches with immune checkpoint inhibitors.”

“For patients with advanced triple-negative breast cancer who have exhausted standard treatment options, expanded access programs can provide additional avenues for care,” said Namita Chittoria, M.D., Assistant Professor at the Huntsman Cancer Institute and the University of Utah, and a member of CytoDyn’s Scientific Advisory Board. “Leronlimab is an investigational therapy being evaluated in this difficult-to-treat setting, and access outside of a clinical study may offer a meaningful option for select patients - both as an additional treatment opportunity and as a way to preserve valuable time with family. Beyond individual use, these programs also inform our understanding of emerging therapies.”

In addition to providing compassionate access, the EAP is expected to generate real-world insights into the biological activity of leronlimab in heavily pretreated patients. Recent data, presented at the American Association for Cancer Research (AACR) Annual Meeting 2026, highlight the potential role of CCR5 inhibition in modulating the tumor microenvironment in metastatic triple-negative breast cancer, with observed associations in PD-L1 expression and broader immune signaling pathways. Together, these findings provide a scientific foundation for the EAP and support continued exploration of leronlimab as a strategy to enhance responses to immune checkpoint inhibitor (ICI) therapies.

To support execution of the program, the Company has engagedWith Every Patient (WEP Clinical) as the clinical research organization to support program execution, including patient identification, site coordination, and regulatory compliance. The EAP is now open for physician referrals, and CytoDyn expects to expand participation as additional sites are activated. The program will operate under applicable U.S. Food and Drug Administration (FDA) guidelines, and additional information for physicians and eligible patients, including referral details, is available on the Company's website at www.cytodyn.com.

About CytoDyn

CytoDyn is a clinical-stage oncology company dedicated to advancing leronlimab, a first-in-class humanized monoclonal antibody that targets the CCR5 receptor, a key regulator of immune function implicated in cancer, infectious diseases, and autoimmune disorders. Guided by a mission to improve patients' quality of life through therapeutic innovation, CytoDyn is committed to integrity, responsibility, and service as it works to bring transformative treatments to patients worldwide.

For more information, please visit www.cytodyn.com and follow us on LinkedIn.

Note Regarding Forward-Looking Statements

This news release may contain forward-looking statements relating to, among other things, the mechanism of action of leronlimab, clinical trial results, product development, market position, future operating and financial performance, and business strategy. The reader is cautioned not to rely on these statements, which are based on current expectations of future events. For important information about these statements and our Company, including the risks, uncertainties and other factors that could cause actual results to vary materially from the assumptions, expectations and projections expressed in any forward-looking statements, the reader should review our Annual Report on Form 10-K for the fiscal year ended May 31, 2025, including the section captioned "Forward-Looking Statements" and in Item 1A, as well as subsequent reports filed with the Securities and Exchange Commission. CytoDyn Inc. does not undertake to update any forward-looking statement as a result of new information or future events or developments except as required by applicable law.

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